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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/249,689	05/26/1994	PAUL R. SCHIMMEL	MIT5261	9517

7590 01/11/2002

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EXAMINER

BRUSCA, JOHN S

ART UNIT PAPER NUMBER

1631

DATE MAILED: 01/11/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/249,689

Applicant(s)

SCHIMMEL, PAUL R.

Examiner

John S Brusca

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3-10,14-16 and 20 is/are allowed.
- 6) ☒ Claim(s) 11-13,17-19 and 21 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Terminal Disclaimer

1. The terminal disclaimer filed on 05 July 2001 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of Application No. 07/929834 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 112

2. The rejection of claims 1 and 3-21 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention in the Examiner's Answer mailed 22 January 1997 is withdrawn as stated in the decision of the Board of Patent Appeals and Interferences mailed 30 April 2001.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 11-13, 17-19, and 21 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention in the decision of the Board of Patent Appeals and Interferences under 37 CFR § 1.196(b) mailed 30 April 2001 is maintained for reasons of record.

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4. Applicant's arguments filed 05 July 2001 have been fully considered but they are not persuasive. The applicants state that the amendment to claims 11-13, 17-19, and 21 further limiting the claimed compounds to compounds that form hydrogen bonds with the targeted RNA results in compounds that are described. The applicants further argue without evidence that knowledge of the structure of the critical region in the minor groove is sufficient to describe the structure of the claimed inhibitory compound that binds the critical region. It is not clear from the specification how knowledge of a critical region in a minor groove is sufficient to describe the structure of the claimed compounds. It is apparent from instant claim 1 that step (e) must be performed to determine the structure of the claimed compound after the critical minor groove site is determined, and the specification further shows on pages 37-39 methods of performing step (e) that are required before the structure of the claimed compounds can be determined. However, the instant specification fails to describe any structures of either a critical region in the minor groove of targeted RNA molecules which can be bound by an inhibitory compound (the substrate of the claimed compound) or any structures of an inhibitory compound that binds a critical site in a minor groove of a targeted RNA molecule (the claimed compound). The written description requirement of 35 U.S.C. § 112, first paragraph is distinct from the enablement requirement, and what is enabled is not necessarily described. Because the specification fails to describe the structure of the claimed compounds, the rejection is maintained.

Double Patenting

5. The provisional rejection of claims 11, 12, and 17-19 under 35 U.S.C. 101 as claiming the same invention as that of claims 15-19 of copending Application No. 07/929834 in the

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Examiner's Answer mailed 22 January 1997 is withdrawn in view of the amendment received 05 July 2001 and the cancellation of claims 15-19 in copending Application No. 07/929834.

6. The provisional rejection of claims 1, 3-6, 8-10, 13-16, 20, and 21 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 8-10, 12-14, and 22 of copending Application No. 07/929834 in the Examiner's Answer mailed 22 January 1997 is withdrawn in view of the Terminal Disclaimer received 05 July 2001.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 703 308-4231. The examiner can normally be reached on M_F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703 308-4025. The fax phone numbers for

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the organization where this application or proceeding is assigned are 703 746-5137 for regular communications and 703 746-5137 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

John S. Brusca
Primary Examiner
Art Unit 1631

jsb
January 9, 2002